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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,352	01/11/2002	Bernard Charles Sherman	2051-44	2443

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,352	SHERMAN, BERNARD CHARLES	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Response and Amendment filed 12/12/03

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1,6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong (USPN 5,492,904) in view of Sjoerdsma (USPN 4,189,492). The claims are drawn to tablet formulation comprising fosinopril sodium, and a lubricant. The lubricant is recited as zinc stearate.

Wong et al discloses a tablet comprising fosinopril sodium, lactose and stearic acid (col. 4, lin. 30 – 58). The reference however does not disclose zinc stearate as the lubricant.

Sjoerdsma discloses an anti-hypertensive tablet formulation where zinc stearate is used to lubricate the formulation (col. 4, lin. 28 – 30). It would be obvious to a skilled artisan to use the zinc stearate in order to lubricate the granules of the tablet formulation and improve stability.

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With regard to claim 7, which discloses specific concentrations of the lubricant, it is the position of the examiner that these concentrations do not impart patentability on the claims. The art presents a general combination of lubricant and fosinopril sodium. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With this in mind it would have been obvious to one of ordinary skill in the art to substitute the lubricant of Sjoerdsma in order to lubricate the tablet formulation and improve stability. A skilled artisan would have been motivated to modify the formulation presented in order to optimize the delivery of the active agent. It would have been obvious to combine and optimize the formulations of the prior art with the expected result of an anti-hypertensive tablet formulation with improved stability.

Response to Arguments

4. Applicant's arguments filed 12/12/03 have been fully considered but they are not persuasive. Applicant argues that:

- a. The art does not address the problem of the instant invention

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b. There is no motivation to combine the teachings of Wong and Sjoerdsma

5. With regard to arguments a. it is the position of the examiner that the problem addressed in the specification of the instant claims is not represented in the instant claims, and thereby cannot be given patentable weight. The claims are drawn to a tablet comprising a drug, lubricant and a filler. The combination of lubricants to provide stability to pharmaceutical formulation is well known in the art, and zinc stearate is very well known in the art. The fact that the art is silent to an unclaimed element of the invention has no bearing on the patentability of the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the problem of using zinc stearate or stearic acid to reduce the degradation products of the composition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding argument b., it is the position of the examiner that the combination provides sufficient motivation. Wong discloses a tablet formulation comprising fosinopril sodium along with a lubricant. The fact that the active agent is secondary is irrelevant since the opened claims language does not exclude further active agents. Furthermore the inclusion of lactose and other lubricants are very well known in the art. Barring a showing of criticality to the inclusion of zinc stearate over any other lubricant, would be required to establish the patentability of the formulation. Since Wong provides the basic formulation, save the specific lubricant of newly amended claims, and Sjoerdsma provides a similar tablet formulation comprising an active agent, lactose and a lubricant (zinc stearate), the motivation would be to improve the stability of the

formulation and properly lubricate the tableting formulation. It remains the position of the examiner that barring a showing of criticality to the specific lubricant over those of the prior art combination at a particular concentration where an unexpected result is reached, the claims will remain obviated by the prior art.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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